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PATENT
Attorney Docket No.: VIVOR1420-1
(073799-1107)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Soon-Shiong *et al.*

Title: CYTOPROTECTIVE BIOCOMPATIBLE CONTAINMENT SYSTEM FOR BIOLOGICALLY ACTIVE MATERIALS AND METHODS OF MAKING SAME

CERTIFICATE OF FACSIMILE TRANSMISSION
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Stephen E. Reiter
(Printed Name)

(Signature)

January 21, 2003
(Date of Deposit)

Appl. No.: 10/029,582

Filed: December 20, 2001

Examiner: D. Jones

Art Unit: 1616

Commissioner for Patents
Washington, D.C. 20231

REPLY UNDER 37 C.F.R. § 1.111

Sir:

Responsive to the Office Action dated November 18, 2002 ("the Office Action"), please consider the following Remarks.

REMARKS

The present invention provides both microcapsules and macrocapsules which have been developed for the encapsulation of biologically active materials therein. Such capsules have at least one biocompatible gellable material, wherein at least the outer layer of the capsule is covalently crosslinked and optionally polyionically crosslinked (or, in the case of macrocapsules comprising microcapsules therein, either polyionically crosslinked, covalently crosslinked, or both polyionically crosslinked and covalently crosslinked), but not ionically crosslinked.

The capsules are highly useful because they permit enhanced migration and aggregation of the biologically active material within the capsule and enhanced control over the release rates of the biologically active material or components secreted by the biologically active material. The capsules also decrease the risk of rejection and/or biomineralization such that the biologically active material within the capsule retains a significant proportion of the functionality of the unencapsulated biologically active material.

Election/Restriction

The restriction of claims 1-64 under 35 U.S.C. § 121 is respectfully traversed. As a preliminary matter, please note that claims 7-38 (Group II) were cancelled on December 20, 2001 upon filing of the above-identified application.

With respect to the remaining claims, it is respectfully submitted that all of the claims of Groups I and III-XII should be grouped together because a search of all claims in one case would not present a serious burden to the Examiner. MPEP § 803 states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." Thus, the Patent Office mandates examination of the entire application where such search and examination can be made *without* serious burden.

In the present case, search of more than one restriction group does not impose a serious burden upon the Examiner, as a search concerning the patentability of the claims of one group is likely to uncover art of interest to the remaining groups. For example, the search of art related to microcapsules should presumably result in information useful to consideration of claims drawn to methods of making microcapsules. Necessarily, that information used to examine patentability of the product will be relevant to the patentability of a method of making that product. Likewise, the search of art related to microcapsules should presumably result in information useful to consideration of macrocapsules, especially macrocapsules which contain microcapsules therein. Any additional search that would be needed would not be an undue

burden on the Examiner. Accordingly, in the interest of efficient advancement of prosecution, it is respectfully requested that the Examiner reconsider and withdraw the restriction requirement.

In the absence of rejoining all of the restriction groups, those inventions which are in the same class should be examined together. For example, Groups III-VI have each been classified into class 428 (subclasses 402.2 and 321.5), and Groups VII-XI have each been classified into class 424 (subclass 520). Searching the claims in any one of these groups would involve searching in the same patent class as other groups. To the extent that an additional search may be required, such additional searching would not be an undue burden on the Examiner.

At the absolute minimum, all inventions which fall into the same class and the same subclass should be grouped together. Specifically, Groups VII-XII should be examined together because the Examiner has classified each of these groups into class 424, subclass 520. Examining all of the groups together would not be an undue burden because a single search in a single class/subclass would reveal art of potential relevance to 6 different groups of claims. In fact, it appears that it would be a greater burden on the Examiner to search and re-search the same class and subclass over and over again than to search the same class and subclass only once.

In order to be fully responsive, Applicants hereby elect the claim in Group VII (i.e., claim 53, drawn to a microcapsule containing at least one cell aggregate therein) with traverse. Non-elected claims 1-6, 39-52 and 54-64 are retained in the application pending final disposition of the elected claims.

The further requirement to elect a single disclosed species under 35 U.S.C. 121 is respectfully traversed. Under 37 C.F.R. 1.146, "if [the] application contains claims directed to more than a reasonable number of species, the Examiner may require restriction of the claims to not more than a *reasonable number of species* before taking further action in the application." (emphasis added). It is respectfully submitted that the Examiner has not demonstrated that there is not a reasonable number of species in the claims. It would not be an undue burden on the

Examiner to search a microcapsule or macrocapsule with more than one biologically active material. Searches related to such capsules with one biologically active material would very likely uncover information related to capsules with a different biologically active material.

Even if the Examiner believes there are claims which are not directed to a reasonable number of species, 37 C.F.R. 1.146 mandates that the Examiner require restriction not to a *single* disclosed species, but to a reasonable *number* of species. The Examiner therefore is requested to withdraw the election of species requirement or to combine two or more species for election. Reconsideration and withdrawal of the requirement for election of species are therefore respectfully requested.

In order to be fully responsive, Applicants hereby elect pancreatic islet cells with traverse. Non-elected species are retained in the application pending final disposition of the elected claims.

CONCLUSION

In view of the above remarks, prompt and favorable action on all claims is respectfully requested. In the event any issues remain to be resolved in view of this communication, the Examiner is invited to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: January 21, 2003

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